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(Acts whose publication is obligatory)

歐盟一般食品法 **Regulation (EC) No 178/2002**

歐洲議會和歐盟理事會 2002 年 1 月 28 日第 853 號有關食品規章

REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 28 January2002

laying down the general principles and requirements of food law, establishing the European Food

SafetyAuthorityand laying down procedures in matters of food safety

Amended by:

►**M1**	Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003	L 245	4	29.9.2003
►**M2**	Commission Regulation (EC) No 575/2006 of 7 April 2006	L 100	3	8.4.2006
►**M3**	Commission Regulation (EC) No 202/2008 of 4 March 2008	L 60	17	5.3.2008
►**M4**	Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009	L 188	14	18.7.2009

一、法規重點摘要：

於 2005 年 1 月 1 日起一般食品法(178/2002 號法規生效，並同時成立歐洲食品安全局(European Food Sfety Authority, EFSF)，以協調各會員國執行與食品安全有關之法規，如食品之可追溯性、防止有害食品（含有害物質）進入市場、食品供應鏈業者（含進出口商）之義務（包括配合實施歐盟食品及飼料快速警報系統）、標示規範、不合符食品安全標準時須至市場撤回之規定。

歐盟食物鏈及動物健康常務委員會（Standing Committee on the Food Chain and Animal Health）為協調各會員國執行上述法規有關食品之可追溯性、防止有害食品進入市場、食品業者之義務及對進出口商之要求(178/2002 號法規第 11,12 及 16 至 20 條）等一般原則及基本規範，已制定指導綱領，並同時協助相關業者瞭解，以徹底落實相關規範。相關新規範將適用於所有食品、動物飼料、動

物用藥、保育類植物、肥料以及所有食物鏈業者，包括農場經營、食品之加工、運輸、儲存、配送及零售等。

另外，在標示規範方面，歐盟為在食物鏈建立可追溯性系統，所有食品及飼料均須標示生產者之姓名、地址、產品名稱及交易日期，相關資料須保存至少 5 年，以供追查之需。該法規第 18 條雖未明確規範標示資料，惟基本上應包括下列兩類資訊：

（1）供應商姓名地址及其供應之產品名稱、銷售對象姓名地址及銷售產品名稱、交易或交貨日期。

（2）產品之交易量、條碼、其他相關資訊（如定量包裝或散裝、水果或蔬菜種類、原料或加工產品）。該可追溯性法規（或標示規範）雖未強制要求第三國出口商配合執行，惟輸入歐盟之進口產品須落實相關規定，為避免重新黏貼標示之困擾，歐盟進口商勢必將要求出口商配合實施。

其他相關規定尚包括：

（1）發現食品不符食品安全標準時要求至市場撤回之規定。

（2）食品業者之義務【包括配合實施歐盟食品及飼料快速警報系統（Rapid Alert System for Food and Feed, RASFF）】。

此外，協調歐盟各會員國之食品衛生法(第 852/2004 號規定)將於 2006 年 1 月生效，其中有關動物用藥、保育類植物等相關規範亦須配合本項規定實施。

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
歐洲議會與歐盟市議會

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95, 133 and Article 152(4)(b) thereof,
考慮歐盟建立的條約，尤其是其中的第 37、95、133、及 152(4)(b)條

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Having regard to the opinion of the Committee of the Regions (3),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (4),

Whereas:
然而

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.
食品自由流通的安全及合乎衛生的食物在內部市場是很重要的部分，並且對市民的健康、其社經福利造成明顯之影響。

(2) A high level of protection of human life and health should be assured in the pursuit of Community policies.
在執行聯盟政策時，應確保能高度保護人類生命及健康。

(3) The free movement of food and feed within the Community can be achieved only if food and feed safety requirements do not differ significantly from Member State to Member State.
倘若在會員國間之食品與飼料安全沒有明顯不同要求之下，在聯盟內之食品、飼料可以自由流通。

(4) There are important differences in relation to concepts, principles and procedures between the food laws of the Member States. When Member States adopt measures governing food, these differences may impede the free movement of food, create unequal conditions of competition, and may thereby directly affect the functioning of the internal market.
各會員國之間的食品法律、原則、概念有明顯的差異。當會員國採用管理食品的措施時，這些差異可能會阻礙食品的自由流通，產生不平等的競爭情況，且可能直接影響內部市場的功能。

(5) Accordingly, it is necessary to approximate these concepts, principles and procedures so as to form a common basis for measures governing food and feed taken in the Member States and at Community level. It is however necessary to provide for sufficient time for the adaptation of any conflicting provisions in existing legislation, both at national and Community level, and to provide that, pending such adaptation, the relevant legislation be applied in the light of the principles set out in the present Regulation.
於是，需要去瞭解這些概念、原則及程序，以便建立會員國與聯盟層級執行食品及飼料之一般基礎措施。然而，在現有的立法下，需要提供足夠的時間去執行受爭議的條款，在執行期間，並在現有法規的原則下，相關的立法可以被執行採用。

(6) Water is ingested directly or indirectly like other foods, thereby contributing to the

overall exposure of a consumer to ingested substances, including chemical and microbiological contaminants. However, as the quality of water intended for human consumption is already controlled by Council Directives 80/778/EEC (5) and 98/ 83/EC (6), it suffices to consider water after the point of compliance referred to in Article 6 of Directive 98/83/ EC.
水是直接攝取吸收或藉由食物攝取吸收，因此消費者有可能暴露在包括化學或微生物污染物的攝取的物質下。然而，飲用水的品質已經由指令 80/778/EEC (5) 與 98/ 83/EC (6)管控，符合指令 98/83/ EC 的水視為飲用水。

(7) Within the context of food law it is appropriate to include requirements for feed, including its production and use where that feed is intended for food-producing animals. This is without prejudice to the similar requirements which have been applied so far and which will be applied in the future in feed legislation applicable to all animals, including pets.
在食品法令的範疇下，包括對飼料的要求、飼料的製造與使用。皆不違反現行之相關要求，且適用於未來的動物飼料的法律中。

(8) The Community has chosen a high level of health protection as appropriate in the development of food law, which it applies in a non-discriminatory manner whether food or feed is traded on the internal market or internationally.
在建立食品法律時，不論食品或飼料是在內部市場或國際間流通。歐盟已經選擇健康的高標準。

(9) It is necessary to ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food law, its scientific basis and the structures and independence of the institutions protecting health and other interests.
在食品法律的基礎下，需要確認消費者與業者在做決定時是有信心的，也確保其科學基礎、結構與保障健康及其他權益建立的獨立性。

(10) Experience has shown that it is necessary to adopt measures aimed at guaranteeing that unsafe food is not placed on the market and at ensuring that systems exist to identify and respond to food safety problems in order to ensure the proper functioning of the internal market and to protect human health. Similar issues relating to feed safety should be addressed.
為了確保內部市場能適當的作用，經驗顯示，實行保證不安全的食品不上市、辨識及反應食品安全系統的措施是必要的。相關的飼料安全與相關的議題已被提及。

(11) In order to take a sufficiently comprehensive and integrated approach to food safety, there should be a broad definition of food law covering a wide range of provisions with a direct or indirect effect on the safety of food and feed, including provisions on materials and articles in contact with food, animal feed and other agricultural inputs at the level of primary production.
為了讓食品安全能採取足夠、通盤的方法，應有廣泛的食品法令定義，涵蓋直接或間接對飼料或食品的影響，包括材料的條款或與食品、動物飼料及其他農產品輸入皆在初級生產的層級內之相關條款。

(12) In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety.
為了確認食品的安全性，需要考慮食品製造鏈的所有部份，做為初級生產、動物飼料的製造、販售、食品供給到消費者的一至連貫性。因為各階段可能有對食品安全的潛在衝擊。

(13) Experience has shown that for this reason it is necessary to consider the production, manufacture, transport and distribution of feed given to food-producing animals, including the production of animals which may be used as feed on fish farms, since the inadvertent or deliberate contamination of feed, and adulteration or fraudulent or other bad practices in relation to it, may give rise to a direct or indirect impact on food safety.
經驗顯示這些原因需要去考慮飼料的生產、加工、運輸及配送，包括由動物製造準備用來做為養殖場的飼料，因為有意或無意的飼料污染、劣質或其他不好的相關案例，可能會產生直接或間接對食品安全的衝擊。

(14) For the same reason, it is necessary to consider other practices and agricultural inputs at the level of primary production and their potential effect on the overall safety of food.
相同的理由，在初級生產的層級，需要考慮其他規範與農產品的輸入及其他潛在食品安全性的影響。

(15) Networking of laboratories of excellence, at regional and/or interregional level, with the aim of ensuring continuous monitoring of food safety, could play an important role in the prevention of potential health risks for citizens.
合格實驗室網絡，在區域/或區域間的層級，在確保食品安全的持續監控下，可

扮演對市民潛在健康危害的預防角色。

(16) Measures adopted by the Member States and the Community governing food and feed should generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure. Recourse to a risk analysis prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs.

(17) Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis - risk assessment, risk management, and risk communication - provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health.
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(18) In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.
為了對食品法律的科學基礎有信心，在現有的科學資訊及數據的基礎下，應該以獨立、有目的且公開的態度執行風險評估。

(19) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.
科學的風險評估是不能單獨進行的，在某些案例中，應依所有提供的資訊做風險評估，考慮相關事件的其它因子應該合法地考慮包括社會、經濟、傳統、道德及環境因子及管控的可行性。

(20) The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle.
已建立預防原則去確保聯盟的健康保障，因此提高食品或飼料的自由流通屏障。因此使用此原則時，需要採用一致的基礎。

(21) In those specific circumstances where a risk to life or health exists but scientific

uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community.
在這些特定的情況，生命或健康存在的風險存在，但是科學不確定度持續，預防原則提供一機制去決定風險評估措施或其他行動，為了確保聯盟高度健康保護。

(22) Food safety and the protection of consumer's interests is of increasing concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisations. It is necessary to ensure that consumer confidence and the confidence of trading partners is secured through the open and transparent development of food law and through public authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health.
食品安全與消費者權益對一般公眾的關心、非政府組織的保護是高度關心的、專業的組織、國際貿易間的組織。需要去確認消費者的信賴度與業者的信賴度是安全的，經由開放與公開食品法律發展，由公家機關採取適當的程序去告知大眾有合理的理由去懷疑食品可能存在對健康的危害。

(23) The safety and confidence of consumers within the Community, and in third countries, are of paramount importance. The Community is a major global trader in food and feed and, in this context, it has entered into international trade agreements, it contributes to the development of international standards which underpin food law, and it supports the principles of free trade in safe feed and safe, wholesome food in a non-discriminatory manner, following fair and ethical trading practices.
在聯盟內消費者信心與安全，在第三國是很重要的。聯盟是食品與飼料的主要的全球貿易商，在此範圍內，已進入國際貿易協定，在食品法律的基礎下，其導致食品法律的發展、支持自由貿易在安全飼料、在非區別行為的所有食品，公正與種族貿易規範的原則。

(24) It is necessary to ensure that food and feed exported or re-exported from the Community complies with Community law or the requirements set up by the importing country. In other circumstances, food and feed can only be exported or re-exported if the importing country has expressly agreed. However, it is necessary to ensure that even where there is agreement of the importing country, food injurious to health or unsafe feed is not exported or re-exported.
必須確認食品及飼料出國或再次從歐盟出口遵照聯盟或進口國建立的要求。在其他情況，如果進口國已經表示同意，食品與飼料只可以被出口或再次出口。然而，需要確認有進口國的許可，傷害健康的食品或不安全的飼料不可出口或再次出

口。

(25) It is necessary to establish the general principles upon which food and feed may be traded and the objectives and principles for the contribution of the Community to developing international standards and trade agreements.
在食品與飼料買賣下，需要建立一般原則及目標讓聯盟發展國際標準及貿易協定。

(26) Some Member States have adopted horizontal legislation on food safety imposing, in particular, a general obligation on economic operators to market only food that is safe. However, these Member States apply different basic criteria for establishing whether a food is safe. Given these different approaches, and in the absence of horizontal legislation in other Member States, barriers to trade in foods are liable to arise. Similarly such barriers may arise to trade in feed.
在食品安全的前提下，一些會員國已經採用水平立法，尤其對業者在市場的責任，只有食品是安全的。然而，這些會員國採用不同的基礎標準去建立是否食品是安全的。這些不同方法，在缺乏其他會員國的水平立法下，食品的貿易障礙是容易發生的。同樣的，這些障礙也可能發生在飼料的貿易中。

(27) It is therefore necessary to establish general requirements for only safe food and feed to be placed on the market, to ensure that the internal market in such products functions effectively.
因此針對上市的安全食品及飼料是必須建立一般要求的，去確認這些產品的功效在國內市場是有效的。

(28) Experience has shown that the functioning of the internal market in food or feed can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.

(29) It is necessary to ensure that a food or feed business including an importer can identify at least the business from which the food, feed, animal or substance that may be incorporated into a food or feed has been supplied, to ensure that on investigation, traceability can be assured at all stages.

(30) A food business operator is best placed to devise a safe system for supplying food

and ensuring that the food it supplies is safe; thus, it should have primary legal responsibility for ensuring food safety. Although this principle exists in some Member States and areas of food law, in other areas this is either not explicit or else responsibility is assumed by the competent authorities of the Member State through the control activities they carry out. Such disparities are liable to create barriers to trade and distort competition between food business operators in different Member States.

(31) Similar requirements should apply to feed and feed business operators.

(32) The scientific and technical basis of Community legislation relating to the safety of food and feed should contribute to the achievement of a high level of health protection within the Community. The Community should have access to high-quality, independent and efficient scientific and technical support.

(33) The scientific and technical issues in relation to food and feed safety are becoming increasingly important and complex. The establishment of a European Food Safety Authority, hereinafter referred to as 'the Authority', should reinforce the present system of scientific and technical support which is no longer able to respond to increasing demands on it.

(34) Pursuant to the general principles of food law, the Authority should take on the role of an independent scientific point of reference in risk assessment and in so doing should assist in ensuring the smooth functioning of the internal market. It may be called upon to give opinions on contentious scientific issues, thereby enabling the Community institutions and Member States to take informed risk management decisions necessary to ensure food and feed safety whilst helping avoid the fragmentation of the internal market through the adoption of unjustified or unnecessary obstacles to the free movement of food and feed.

(35) The Authority should be an independent scientific source of advice, information and risk communication in order to improve consumer confidence; nevertheless, in order to promote coherence between the risk assessment, risk management and risk communication functions, the link between risk assessors and risk managers should be strengthened.

(36) The Authority should provide a comprehensive independent scientific view of the safety and other aspects of the whole food and feed supple chains, which implies

wide-ranging responsibilities for the Authority. These should included issues having a direct or indirect impact on the safety of the food and feed supply chains, animal health and welfare, and plant health, However, it is necessary to ensure that the Authority focuses on food safety, so its mission in relation to animal health, animal welfare and plant health issues that are not lined to the safety of the food supple chain should be limited to the provision of scientific opinions. The Authority's mission should also cover scientific advise and scientific and technical support on human nutrition in relation to community legislation and assistance to the commission at its request on communication linked to community health programmes.
(36) 權責機關應提供有關安全和所有食品飼料供應鏈之全面獨立之科學見解，以表示權責機關多方面之責任。這些應包括有關直接或間接影響食品飼料鏈安全、動物健康及福利和植物健康之問題。但是，其應確保權責機關專注於食品安全，所以，關於動物健康、動物福利以及植物健康，但不屬於食品供應鏈安全之任務應限制於科學意見內。權責機關之任務應包括科學建議和科學、技術上關於人體營養之聯盟法規和在聯盟要求下對公共安全計畫溝通之協助。

(37) Since some products authorised under food law such as pesticides or additives in animal feed may involve risks to the environment or to the safety of workers, some environmental and worker protection aspects should also be assessed by the Authority in accordance with the relevant legislation.
(37) 鑿於某些經食品法批准之產品例如:在動物飼料中之殺蟲劑或添加物可能有對環境或員工安全之風險，其環境及員工保護方面也應被權責機關依有關之法規進行評估。

(38) In order to avoid duplicated scientific assessments and related scientific opinions on genetically modified organisms (GMOs), the Authority should also provide scientific opinions on products other than food and feed relating to GMOs as defined by Directive 2001/18/EC (1) and without prejudice to the procedures established therein.
(38) 為了防止基因改造產品重複的科學評估和相關之科學意見，權責機關應依據指令 2001/18/EC (1) 提供除了有關基因改造之飼料食品產品外的科學意見，並且不損害在其內訂定之程序。

(39) The Authority should contribute through the provision of support on scientific matters, to the Community's and Member States' role in the development and establishment of international food safety standards and trade agreements.
(39) 權責機關應在科學事件上提供支持，對聯盟及會員國在國際食品安全標準及貿易協定之建立和創建之角色有所貢獻。

(40) The confidence of the Community institutions, the general public and interested parties in the Authority is essential. For this reason, it is vital to ensure its independence, high scientific quality, transparency and efficiency. Cooperation with Member States is also indispensable.
(40) 聯盟機構與一般大眾以及權責機關內之有興趣之第三機構之信心是極重要的。為此目的，維持其獨立性高科學品質透明化和有效性是不可或缺的。和其他會員國合作也是必須的。

(41) To that effect the Management Board should be appointed in such a way as to secure the highest standard of competence, a broad range of relevant expertise, for instance in management and in public administration, and the broadest possible geographic distribution within the Union. This should be facilitated by a rotation of the different countries of origin of the members of the Management Board without any post being reserved for nationals of any specific Member State.
(41) 為此，管理會應基於鞏固權責之最高標準，大範圍的相關專業，例如在管理方面和公共管理，以及在歐盟內最廣闊之可能的地理分布。此管理可經由沒有任何特定之會員國經營。並由管理會內之不同國家之成員的輪替管理。

(42) The Authority should have the means to perform all the tasks required to enable it to carry out its role.
(42) 權責機關應有完成所有必須之作業之法以能夠執行其任務。

(43) The Management Board should have the necessary request on communication linked to Community health powers to establish the budget, check its implementation., draw up internal rules, adopt financial regulations, appoint members of the Scientific Panels and appoint the Executive Director.
(43) 管理會應須要求在衛生權力之溝通上建立其預算，檢查其執行、建立內部規定、通過經濟法規、指定科學小組成員和執行組長。

(44) The Authority should cooperate closely with competent bodies in the Member States if it is to operate effectively. An Advisory Forum should be created in order to advise the Executive Director, to constitute a mechanism of exchange of information, and to ensure close cooperation in particular with regard to the networking system. Cooperation and appropriate exchange of information should also minimise the potential for diverging scientific opinions.
(44) 權責機關如果要有效的執行，應和會員國之權責機構密切的合作。諮詢論壇會應被成立以建議其執行長建立資訊交換之程序並確保資訊系統的密切合作。

合作及適時的交換資訊也可以減少潛在的科學分歧意見。

(45) The Authority should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence. It is necessary to reorganise these Committees to ensure greater scientific consistency in relation to the food supply chain and to enable them to work more effectively. A Scientific Committee and Permanent Scientific Panels should therefore be set up within the Authority to provide these opinions.
(45) 權責機關應掌管執委會之科學委員會，並在權責內發布科學意見。重新組織這些委員是必須的,用以確保有關食品供應鏈能有更好的科學一致性以及使其能夠更有效率的工作。因此在權責範圍內需建立科學委員會和永久科學小組。

(46) In order to guarantee independence, members of the Scientific Committee and Panels should be independent scientists recruited on the basis of an open application procedure.
(46) 為了保證獨立性，科學委員會之成員和小組應為公開徵求之獨立科學家。

(47) The Authority's role as an independent scientific point of reference means that a scientific opinion may be requested not only by the Commission, but also by the European Parliament and the Member States. In order to ensure the manageability and consistency of the process of scientific advice, the Authority should be able to refuse or amend a request providing justification for this and on the basis of predetermined criteria. Steps should also be taken to help avoid diverging scientific opinions and, in the event of diverging scientific opinions.

(48) The Authority should also be able to commission scientific studies necessary for the accomplishment of its duties, while ensuring that the links established by it with the Commission and the Member States prevent duplication of effort. It should be done in an open and transparent fashion and the Authority should take into account existing Community expertise and structures.

(49) The lack of an effective system of collection and analysis at Community level of data on the food supply chain is recognised as a major shortcoming. A system for the collection and analysis of relevant data in the fields covered by the Authority should therefore be set up, in the form of a network coordinated by the Authority. A review of Community data collection networks already existing in the fields covered by the Authority is called for.

(50) Improved identification of emerging risks may in the long term be a major preventive instrument at the disposal of the Member States and the Community in the exercise of its policies. It is therefore necessary to assign to the Authority an anticipatory task of collecting information and exercising vigilance and providing evaluation of and information on emerging risks with a view to their prevention.

(51) The establishment of the Authority should enable Member States to become more closely involved in scientific procedures. There should therefore be close cooperation between the Authority and the Member States for this purpose. In particular, the Authority should be able to assign certain tasks to organisations in the Member States.

(52) It is necessary to ensure that a balance is struck between the need to use national organisations to carry out tasks for the Authority and the need to ensure for the purposes of overall consistency that such tasks are carried out in line with the criteria established for such tasks. Existing procedures for the allocation of scientific tasks to the Member States, in particular with regard to the evaluation of dossiers presented by industry for the authorisation of certain substances, products or procedures, should be re-examined within a year with the objective of taking into account the establishment of the Authority and the new facilities it offers, the evaluation procedures remaining at least as stringent as before.

(53) The Commission remains fully responsible for communicating risk management measures. The appropriate information should therefore be exchanged between the Authority and the Commission. Close cooperation between the Authority, the Commission and the Member States is also necessary to ensure the coherence of the global communication process.

(54) The independence of the Authority and its role in informing the public mean that it should be able to communicate autonomously in the fields falling within its competence, its purpose being to provide objective, reliable and easily understandable information.

(55) Appropriate cooperation with the Member States and other interested parties is necessary in the specific field of public information campaigns to take into account any regional parameters and any correlation with health policy.

(56) In addition to its operating principles based on independence and transparency, the Authority should be an organisation open to contacts with consumers and other

interested groups.

(57) The Authority should be financed by the general budget of the European Union. However, in the light of experience acquired, in particular with regard to the processing of authorisation dossiers presented by industry, the possibility of fees should be examined within three years following the entry into force of this Regulation. The Community budgetary procedure remains applicable as far as any subsidies chargeable to the general budget of the European Union are concerned. Moreover, the auditing of accounts should be undertaken by the Court of Auditors.

(58) It is necessary to allow for the participation of European countries which are not members of the European Union and which have concluded agreements obliging them to transpose and implement the body of Community law in the field covered by this Regulation.

(59) A system for rapid alert already exists in the framework of Council Directive 92/59/EEC of 29 June 1992 on general product safety (1). The scope of the existing system includes food and industrial products but not feed. Recent food crises have demonstrated the need to set up an improved and broadened rapid alert system covering food and feed. This revised system should be managed by the Commission and include as members of the network the Member States, the Commission and the Authority. The system should not cover the Community arrangements for the early exchange of information in the event of a radiological emergency as defined in Council Decision 87/600/Euratom (2).

(60) Recent food safety incidents have demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed should be subject to common measures in the event of a serious risk to human health, animal health or the environment. Such a comprehensive approach to emergency food safety measures should allow effective action to be taken and avoid artificial disparities in the treatment of a serious risk in relation to food or feed.

(61) Recent food crises have also shown the benefits to the Commission of having properly adapted, more rapid procedures for crisis management. These organisational procedures should make it possible to improve coordination of effort and to determine the most effective measures on the basis of the best scientific information. Therefore, revised procedures should take into account the Authority's responsibilities and should

provide for its scientific and technical assistance in the form of advice in the event of a food crisis.

(62) In order to ensure a more effective, comprehensive approach to the food chain, a Committee on the Food Chain and Animal Health should be established to replace the Standing Veterinary Committee, the Standing Committee for Foodstuffs and the Standing Committee for Feedingstuffs. Accordingly, Council Decisions 68/ 361/EEC (1), 69/414/EEC (2), and 70/372/EEC (3), should be repealed. For the same reason the Committee on the Food Chain and Animal Health should also replace the Standing Committee on Plant Health in relation to its competence (for Directives 76/895/EEC (4), 86/ 362/EEC (5), 86/363/EEC (6), 90/642/EEC (7) and 91/ 414/EEC (8)) on plant protection products and the setting of maximum residue levels.

(63) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (9).

(64) It is necessary that operators should have sufficient time to adapt to some of the requirements established by the present Regulation and that the European Food Safety Authority should commence its operations on 1 January 2002.

(65) It is important to avoid confusion between the missions of the Authority and the European Agency for the Evaluation of Medicinal Products (EMEA) established by Council Regulation (EEC) No 2309/93 (10). Consequently, it is necessary to establish that this Regulation is without prejudice to the competence conferred on the EMEA by Community legislation, including powers conferred by Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (11).

(66) It is necessary and appropriate for the achievement of the basic objectives of this Regulation to provide for the approximation of the concepts, principles and procedures forming a common basis for food law in the Community and to establish a European Food Safety Authority. In accordance with the principle of proportionality as set out in Article 5 of the Treaty, this Regulation does not go beyond what is necessary in order to achieve the objectives pursued,

HAVE ADOPTED THIS REGULATION:

CHAPTERI
第 I 章

SCOPE AND DEFINITIONS
範圍與定義

Article 1
第 1 條

Aim and scope
目標與範圍

1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market.
本法規提供確保食品對人體健康及消費者權益高度保護的基礎，尤其考慮供應的食品差異性(包括傳統食品)，以確保內部市場有效率的運作。

It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.
本法規建立了共通的原則及責任。提供健全的科學基礎的方法、有效率的組織安排及程序，去支持食品、飼料安全的事務決定。

2. For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.
第一段的目的，尤其是在歐盟及國內的食品及飼料安全的部分，本法規依據一般食品及飼料的一般原則。

It establishes the European Food Safety Authority.
本法規建立了歐盟食品安全局。

It lays down procedures for matters with a direct or indirect impact on food and feed safety.

本法規也依據針對食品及飼料直接或間接產生衝擊事物的程序。

3. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.
本法規應適用於食品與飼料生產、加工、運送的所有階段。不適用於供應國內私人初級生產之食品、前置處理、製備或儲存的使用。

Article 2
第 2 條

Definition of ‘food’
食品之定義

For the purposes of this Regulation, ‘food’ (or ‘foodstuff’) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.
為了符合本法規的立義，「食品」是指任何不論是否經過加工，供人食用或可合理預期讓人類攝取食用的產品。

‘Food’ includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.
「食品」包括飲料、口香糖；或在製造、前置處理或製備時添加於食品之任何物質，包括水。水的定義需遵循歐盟指令 98/83 第 6 條的要求，且與歐盟指令 80/778 、98/83 的要求一致。

‘Food’ shall not include:
「食品」不包括
(a) feed; 飼料

(b) live animals unless they are prepared for placing on the market for human consumption; 活體動物(除非牠們被備製成產品上市供人食用)

(c) plants prior to harvesting; 採收前的植物

(d) medicinal products within the meaning of Council Directives 65/65/EEC (1) and 92/73/EEC (2); 在議會指令 65/65 及 92/73 中所指的藥物產品

(e) cosmetics within the meaning of Council Directive 76/ 768/EEC (3);
歐盟理事會指令 76/ 768 所指的化妝品

(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC (4);
在歐盟理事會指令 89/622 所指的菸草及菸草製品

(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
在 1961 年 United Nations Single Convention on Narcotic Drugs 及 1971 年 the United Nations Convention on Psychotropic Substances 所指的麻醉劑或精神病用藥

(h) residues and contaminants.
殘留物及污染物

Article 3
第 3 條

Other definitions
其他定義

For the purposes of this Regulation:
依本法規的目的

1. 'food law' means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food producing animals;
「食品法律」指不論是否在聯盟內或國家層級的管理食品，尤其是食品安全的法規、條款、規章。其涵蓋食品生產、加工及運輸的所有階段、生產產品的飼料、或生產食品的動物。

2. 'food business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;
「食品產業」意指任何不論是否為營利、公家或私人的，完成任何關於食品製造、

加工及運送活動的企業。

3. ‘food business operator’ means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;
「食品業者」意指自然人或法人負責確保其所控制的食品營業符合食品法律的要求

4. ‘feed’ (or ‘feedingstuff’) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;
飼料(或食品)意指不論是否經過加工，供給動物食用的任何物質或產品，包括添加物。

5. ‘feed business’ means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;
「飼料產業」意指完成任何飼料生產、製造、加工、儲存、運送或販售之不論是否為營利、公家或私人的行業

6. ‘feed business operator’ means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;
飼料業者意指自然人或法人負責確認在其管控下，飼料業符合食品法律的要求

7. ‘retail’ means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;
零售意指食品的處理與/或加工，在販售點的儲存或送到最終消費者，包括配送末端、供餐經營業者、工廠餐廳、機關供膳、餐廳及其他食品服務業、商店、超級市場、配送中心及大型量販店。

8. ‘placing on the market’ means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;
上市意指食品或飼料為了販售的目的，包括提供作為銷售或任何其他型式的改變，不論是否收費，販售、配送及其他型式的改變。

9. ‘risk’means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
「風險」指對造成健康負面影響的可能性及其影響的嚴重性、隨之發生的危害。

10. ‘risk analysis’ means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
「風險分析」意指三個相互組成的因素過程: 危害評估、危害管理及危害溝通。

11. ‘risk assessment’ means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;
「風險評估」是指以科學為基礎的程序下，以危害辨識、危害鑑定、暴露評估及風險鑑定四項。

12. ‘risk management’ means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;
「風險管理」指不同於風險評估的程序，衡量利益團體諮詢中的替代政策，考慮風險評估或其他合理的因子，如果需要時，選擇適當的預防措施或控管意見。

13. ‘risk communication’ means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;
「風險溝通」指在關於危害及風險、風險相關因子、風險預測的分析程序下，在風險評估者、風險管理者、消費者、飼料及食品業者、學術團體或其他利益團體，包括風險評估示現的闡釋及風險管理決定的基礎，相互交換訊息及意見。

14. ‘hazard’means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;
「危害」表示生物學、化學或物理的物質，存在食品或飼料中可能造成有害健康的潛在問題；

15. ‘traceability’ means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;

「可追溯性」表示具有追蹤食品、飼料、生產食品的動物或物質，或融入至食品或飼料中，或透過產品、加工和配送的階段；

16. ‘stages of production, processing and distribution’ means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;
「生產、加工和配送階段」指包括進口、從初級生產的食品，包括儲存、運輸、銷售或提供給消費者相關的進口、生產、加工、儲存、運送、配送、銷售和供應的任何階段；

17. ‘primary production’ means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;
「初級生產」指初級產品之生產、飼養和生長，包括收獲、擠乳及屠宰前之飼養；亦包括打獵和捕魚及野生產品的收獲。

18. ‘final consumer’ means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.
「最終消費者」指食品最終的消費者，且不會將食品作其他任何食品經銷營業或活動。

CHAPTERII
第 II 章

GENERAL FOOD LAW
一般食品法

Article 4
第 4 條

Scope
範圍

1. This Chapter relates to all stages of the production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.
本章包括所有食品之生產、加工、配送及飼料生產或飼養生產食品的動物的相關

階段。

2. The principles laid down in Articles 5 to 10 shall form a general framework of a horizontal nature to be followed when measures are taken.
應依第 5 條到第 10 條規定形成水平管理架構以展開管理措施。

3. Existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with Articles 5 to 10.
現有的食品法之原則和程序應於 2007 年 1 月 1 日實施以符合第 5 條到第 10 條法規規定。

4. Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in Articles 5 to 10.
屆時，第 2 段中的廢除則應實際考慮現有法令中有關第 5 條到第 10 條所要求的原則。

SECTION 1
第一節

GENERAL PRINCIPLES OF FOOD LAW
食品法之一般原則

Article 5
第 5 條
General objectives
總體目標

1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.
食品法規應追求多項目標，高度保障人類生命和健康，維護消費者權益，包括食品貿易的公平交易，及適當時保護動植物之健康、福利和環境。

2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.
食品法規應促進歐盟內食品和飼料之生產或行銷符合本章之一般共通原則而自

由流通。

3. Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community.
當國際標準之存在或其實施具急迫性時,於食品法規於發展中或決定實行時即應將之列入考量;除非該標準或相關部分標準可能於執行後對符合食品法令之目的為無效或不適當,或有其他科學的理由顯示其在歐盟共同體雖具不同的衛生保護水準但仍被判定為適當的。

Article 6
第 6 條

Risk analysis
風險分析

1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.
為了高度保護人類健康和生命的目標，食品法規應以風險分析為基礎。

2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.
風險評估應以獨立、客觀和透明的科學證據為基礎。

3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.
風險管理應考慮風險估計的結果，尤其是第 22 條法規所提及權責單位的意見，第 7 條法規(1)所說明的條件，考慮其合法原因和謹慎的原則，以達第 5 條法規中食品法之一般目的。

Article 7
第 7 條

Precautionary principle
預防原則

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.
經評估既有訊息後，如已鑑定出具危害健康之可能性，但科學上仍有其不確定性，則可採行暫時之風險管理措施以保護歐盟，並以更進一步之科學資訊做更完整之風險評估。

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.
依第 1 段採用的措施應具適當比例原則，且不應超越保護歐盟原則而限制貿易；亦需考慮技術、經濟及其他相關之可行性要素。應依對生命健康造成風險本質、科學資訊之種類，於合理之期間內審查執行之措施，以釐清科學之不確定性以執行更完整之風險評估。

Article 8
第 8 條
Protection of consumers' interests
消費者利益之保護

1. Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume.
食品法規之訂定應旨在保護消費者權益，且提供消費者有關其選擇消費食品之基本資訊。

It shall aim at the prevention of:
應防止：

(a) fraudulent or deceptive practices;

(a) 欺騙或詐欺的行為；

(b) the adulteration of food; and
(b) 摻假劣質的食品，且；

(c) any other practices which may mislead the consumer.
(c)任何會誤導消費者的其他規範。

SECTION 2
第二節

PRINCIPLES OF TRANSPARENCY
透明原則

Article 9
第 9 條

Public consultation
公開協商

There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.
在準備、評估和修法期間，應直接或透過代表機構以公開且透明化的方式公開進行協商，除非有緊急的情況無法執行。

Article 10
第 10 條

Public information
公開訊息

Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may

present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.
在不違反歐盟及國家相關的法規之情況下，當有合理基礎懷疑食品或飼料可能造成人或動物健康之風險時，依據風險的本質、嚴重性和程度，權責單位應採取適當程序通知一般大眾有關該風險本質對健康的影響，盡可能指出該食品或飼料之種種資訊、食品或飼料之種類，可能存在之風險、所採行之預防、降低或排除該風險之措施。

SECTION 3
第三節

GENERAL OBLIGATIONS OF FOOD TRADE
食品貿易之一般責任

Article 11
第 11 條

Food and feed imported into the Community
輸入歐盟之食品和飼料

Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.
輸入歐盟之食品和飼料於上市時應符合食品法規相關之要求或歐盟之安排，使其至少和前者具同等效果，或者於歐盟和出口國間以特殊之協議來涵括相關之要求。

Article 12
第 12 條
Food and feed exported from the Community
輸出歐盟之食品和飼料

1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and

administrative procedures as may be in force in the importing country.
略

In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.
略

2. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.
略

Article 13
第 13 條
International standards
國際標準

Without prejudice to their rights and obligations, the Community and the Member States shall:
在不違反其權利和義務之前提下，歐盟和會員國應：
(a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards;
(a)共同致力於食品和飼料之衛生檢驗及動植物檢疫措施之國際技術標準的發展；

(b) promote the coordination of work on food and feed standards undertaken by international governmental and nongovernmental organisations;
(b)倡導國際政府和非政府組織推動食品和飼料標準之整合工作；

(c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures;
(c)推動認定食品和飼料相關特定之管理措施間之協議認定；

(d) give particular attention to the special development, financial and trade needs of

developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries;
(d)對於發展中國家之發展、財務和貿易需求須特別的注意，以確保國際標準規範不會對開發中國家的發展、金融、貿易及出口造成不必要的阻礙；

(e) promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced.
增進國際技術標準及食品法規之一致性，以確保歐盟實施之高標準保護目標不致降低。

SECTION 4
第四節

GENERAL REQUIREMENTS OF FOOD LAW
食品法之一般要求

Article 14
第 14 條

Food safety requirements
食品安全要求

1. Food shall not be placed on the market if it is unsafe.
1.不安全之食品不應上市。
2. Food shall be deemed to be unsafe if it is considered to be:
2.應該被認為不安全的食品，如果被視為：

(a) injurious to health;
(a)有害健康；

(b) unfit for human consumption.
(b)不適合人類食用。

3. In determining whether any food is unsafe, regard shall be had:
3.確定任何食品是否是不安全的，應考慮：

(a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and

(a) 該食品之消費者正常使用狀況及其生產、加工和配送間之每一階段之正常狀態；

(b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.
(b)對於提供給消費者的訊息，包括標示上的訊息，或其他消費者一般可普遍取得、有關某特定類食物其有害健康之資訊。

4. In determining whether any food is injurious to health, regard shall be had:
4.在確定某類食品是否對健康有害時，應注意：

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
(a)不僅考慮可能立即性的、或短期的、或長期食用該食品之消費者之健康之影響，甚至對其後代健康之影響；

(b) to the probable cumulative toxic effects;
(b)可能累積的毒性影響；

(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.
(c)供應食物給具敏感特質之特定消費族群。

5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.
5.在判定任何食品是否具不適於人類食用時，應考慮該食品原先即未預設供應給人類食用、或已被異物或他物污染、或腐敗、惡化或腐爛。

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.
6.當一批、一堆或一次發貨量之產品中，其部份產品為不安全時，應假設同批、堆或發貨之產品也都為不安全的，除非已執行詳細的評估，且無法證明剩下之產品為不安全的。

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.
7.食品符合歐盟所規定之特定食品安全要求時，應就其相關之歐盟法令之範疇可判定其為安全的。

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.
8.當食品符合適用於該食品之特定規定時，該符合情況不應成為妨礙權責機關於具有其他理由懷疑該食品的不安全時，要求限制該產品上市或下市之理由。

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.
9.如歐盟無特定之規定時，若符合該食品於歐盟銷售區域國家之國內法令時，該食品應被認為是安全的；該規定應被制訂且不違反條約，特別是其中第 28 條和第 30 條所擬定的。

Article 15
第 15 條
Feed safety requirements
飼料安全要求

1. Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.
略

2. Feed shall be deemed to be unsafe for its intended use if it is considered to:

- have an adverse effect on human or animal health;
- make the food derived from food-producing animals unsafe for human consumption.
略

3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.
略

4. Feed that complies with specific Community provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.
略

5. Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.
略

6. Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law governing feed safety of the Member State in whose territory the feed is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.
略

Article 16
第 16 條

Presentation
描述

Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.
產品之標示、廣告和外觀，包括其形狀、外觀或包裝、使用之包材、安排方式、陳列方式等不應違反特定食品法規之規定、且透過任何媒體傳遞之訊息，不應誤導消費者。

Article 17
第 17 條

Responsibilities
責任

1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.
1. 食品和飼料業者於生產、加工和配送之所有控制階段皆應確保食品和飼料符合食品法規中與他們的活動相關的要求。

2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.
會員國應執行食品法規之要求，並監測及確認食品及飼料業者於生產、加工和配送之所有控制階段皆已符合食品法令之相關要求。

For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.
會員國應維持官方之管制系統及其他活動，包括公開溝通食品及飼料之安全和風險，並提供食品及飼料生產、加工和配送各階段安全性之查核和監控資訊。

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.
會員國應擬訂有關違反法令之管制措施及懲罰規定。該管制措施及懲罰應有效、具比例原則並具嚇阻違法情事之效果。

Article 18
第 18 條

Traceability
可追蹤性

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.
1. 於生產、加工和配送之所有階段皆應建立可追溯食品、飼料及供應食用牲畜及其他被使用而加入食品或飼料之物質之制度。

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.
2. 食品和飼料業者應能判斷辨別其供應食品、飼料及供應食用牲畜及其他被使用而加入食品中或飼料中之物質之客戶。為滿足此要求，食品和飼料業者應有追蹤系統和程序使權責機關要求時提供相關之資訊。

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.
3. 食品和飼料業者應有系統和程序於以辨別其所供應之業者。並於權責機關要求時提供相關之資訊。

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.
4. 市面上的食品或飼料或可能流入歐盟之食品或飼料應依特定法令之相關要求，可透過相關之文件或資訊，並有適當之標示或辨別以供追溯。

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).
5. 相關產業為符合本條文要求可依第 58(2)條之程序具以執行。

關於第 18 條食品可追蹤性的施行細則，則列於 2011 年 9 月 19 日的 COMMISSION IMPLEMENTING REGULATION (EU) No 931/2011 法規，其規定如下:

食品追溯的規定 (Traceability requirements)

1. 食品業者應確保關於被運送之動物性來源食品貨物的資訊，可以讓接受貨物的另一食品業者取得；並且也能使此一資訊讓主管當局取得。 這些資訊包括:

   a. 食品的精確敘述。
   b. 產品的體積或數量。
   c. 發貨之食品業者的姓名及地址。
   d. 貨主的姓名及地址 (如果和發貨之食品業者有所不同)。
   e. 接受貨物之食品業者的姓名及地址。
   f. 貨主的姓名及地址 (如果和接受貨物之食品業者有所不同)。
   g. 如果須要，相關之文件來確認被運送之貨品，如批號 或 貨號。
   h. 貨物發送之日期。

2. 除了歐盟相關法規中關於動物性來源食品的追溯規定外，也應提供前述所提到的相關資訊。

3. 前述所提到的相關資訊，必須每日更新；並將資訊保存到食品可被合理的認定已被食用之日期。

當主管當局要求資訊時，食品業者應提供資訊，不可無故拖延。資訊可被取得的型式由食品供應者來決定，只要前述所提及的資訊可以清楚和明確的被接受貨物的食品業者來獲得和取得。

Article 19
第 19 條

Responsibilities for food: food business operators
食品責任：食品業者

1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of

that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

1.若食品業者考慮或有其他理由認為其已進口、生產、加工、製造或分發的食品未符合食品安全的要求，且產品已脫離原食品業者之直接控制時，則應通報權責機關，依程序從市場中回收指定的食品。產品若已達消費者端，食品業者應有效且確實通知消費者下市該產品之原因，當其他措施皆不足以達到高度保護消費者衛生時，得以從消費者端回收該產品。

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

2.食品業者經營執行零售及配送等不影響包裝、標示、安全或食品的完整性者，在其執行業務範圍內，需啟動程序將不符食品安全要求的產品從市場下市，協助提供需要之訊息去追溯食品，並與生產者、加工者、製造業者/或權責機關配合行動。

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

3.食品業者如有理由相信某上市食品可能對人體健康有害，則應立即通知權責機關。食品業者應通知權責機關有關所採取預防消費者遭受風險之措施，應依據國家法律和法律執行，應於適當時配合權責機關防止、降低或排除食品對最終消費者的危險。

4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

4.食品業者應和權責機構配合行動以避免或降低其供應品或已提供產品所造成

之風險。

Article 20
第 20 條

Responsibilities for feed: feed business operators
供應商責任：經銷商

1. If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

2. A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a feed.

4. Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply or have supplied.

Article 21
第 21 條

Liability
法定責任

The provisions of this Chapter shall be without prejudice to Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (1).
此章法令不應違反 1985 年 7 月 25 日歐盟理事會指令 85/374 /EC 的法規，該法規為關於會員國有責任擬出管理不良產品之法令、法規和行政規定。

CHAPTERIII
第 III 章

EUROPEAN FOOD SAFETY AUTHORITY
歐盟食品安全局

SECTION 1
第一節

MISSION AND TASKS
使命與任務

Article 22
第 22 條
Mission of the Authority
當局之使命

1. A European Food Safety Authority, hereinafter referred to as the'Authority', is hereby established.
1. 成立歐洲食品安全局，以下簡稱本局。

2. The Authority shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on

all matters within these fields and communicate on risks.
2. 本局應提供科學建議、科學和技術支援以支持會員國各方面之立法和政策，凡直接或間接影響食品安全者皆包涵其內，除此外亦應提供相關之自主管理資訊並溝通相關之風險。

3. The Authority shall contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market.
3. 本局應協助高度保護人類的生命和健康，以此進一步考慮動物健康和福利、植物健康和環境。

4. The Authority shall collect and analyse data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.
4.本局應蒐集並且分析數據，執行直接或者間接的對食品安全的影響並描述和監控危險。

5. The mission of the Authority shall also include the provision of:
5. 本局的任務也包括：

(a) scientific advice and scientific and technical support on human nutrition in relation to Community legislation and, at the request of the Commission, assistance concerning communication on nutritional issues within the framework of the Community health programme;
(a) 提供營養上之科學建議、科學和技術之支援以協助立法，應執委會要求協助溝通有關歐盟營養健康計畫架構中的問題；

(b) scientific opinions on other matters relating to animal health and welfare and plant health;
(b) 提供動物健康、福利和植物健康有關其他事情的科學意見；

(c) scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC and without prejudice to the procedures established therein.
略

6. The Authority shall provide scientific opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission.

6.本局應於宗旨範圍內提供歐盟草擬及採用管制方法之科學意見。

7. The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.
7. 本局應以以下特質執行其工作，包括其獨立性、所發佈之優質科學和技術意見，程序和運作之透明化及致力執行工作之投入。

It shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks to these of the Authority.
也應與會員國執行類似工作之權責機構緊密合作。

8. The Authority, Commission and Member States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions.
8. 本局、執委會和會員國應合作以有效促進風險評估、風險管理和風險溝通。

9. The Member States shall cooperate with the Authority to ensure the accomplishment of its mission.
9.會員國應與本局確保達成本局成立之宗旨。

Article 23
第 23 條

Tasks of the Authority
當局之任務

The tasks of the Authority shall be the following:

(a) to provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission;

(b) to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission;

(c) to provide scientific and technical support to the Commission in the areas within its mission and, when so requested, in the interpretation and consideration of risk assessment opinions;

(d) to commission scientific studies necessary for the accomplishment of its mission;

(e) to search for, collect, collate, analyse and summarise scientific and technical data in the fields within its mission;

(f) to undertake action to identify and characterise emerging risks, in the fields within its mission;

(g) to establish a system of networks of organisations operating in the fields within its mission and be responsible for their operation;

(h) to provide scientific and technical assistance, when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed;

(i) to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving cooperation between the Community, applicant countries, international organisations and third countries, in the fields within its mission;

(j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;

(k) to express independently its own conclusions and orientations on matters within its mission;

(l) to undertake any other task assigned to it by the Commission within its mission.

SECTION 2
第二節

ORGANISATION
組織

Article 24
第 24 條

Bodies of the Authority
當局之組成機構

The Authority shall comprise:
(a) a Management Board;
(b) an Executive Director and his staff;
(c) an Advisory Forum;
(d) a Scientific Committee and Scientific Panels.

Article 25
第 25 條

Management Board
管理委員會

1. The Management Board shall be composed of 14 members appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission which includes a number of candidates substantially higher than the number of members to be appointed, plus a representative of the Commission. Four of the members shall have their background in organisations representing consumers and other interests in the food chain.

The list drawn up by the Commission, accompanied by the relevant documentation, shall be forwarded to the European Parliament. As soon as possible and within three months of such communication, the European Parliament may make its views available for consideration by the Council, which will then appoint the Management Board.

The members of the Board shall be appointed in such a way as to secure the highest standards of competence, a broad range of relevant expertise and, consistent with these, the broadest possible geographic distribution within the Union.

2. Members' term of office shall be four years, and may be renewed once. However, for the first mandate, this period shall be six years for half of the members.

3. The Management Board shall adopt the Authority's internal rules on the basis of a proposal by the Executive Director. These rules shall be made public.

4. The Management Board shall elect one of its members as its Chair for a two-year period, which shall be renewable.

5. The Management Board shall adopt its rules of procedure. Unless otherwise provided, the Management Board shall act by a majority of its members.

6. The Management Board shall meet at the invitation of the Chair or at the request of at least a third of its members.

7. The Management Board shall ensure that the Authority carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation.

8. Before 31 January each year, the Management Board shall adopt the Authority's programme of work for the coming year. It shall also adopt a revisable multi-annual programme. The Management Board shall ensure that these programmes are consistent with the Community's legislative and policy priorities in the area of food safety.

Before 30 March each year, the Management Board shall adopt the general report on the Authority's activities for the previous year.

▼M1

9. The financial rules applicable to the Authority shall be adopted by the Management Board after the Commission has been consulted. They may not depart from Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities (26) unless such departure is specifically required for the Authority's operation and the Commission has given its prior consent.

9. The Management Board, having received the Commission's approval and the opinion of the Court of Auditors, shall adopt the Authority's financial regulation which specifies in particular the procedure for drawing up and implementing the Authority's budget, in accordance with Article 142 of the Financial Regulation of 21 December 1977 applicable to the general budget of the European Communities (1)

and with the legislative requirements concerning investigations conducted by the European Anti-Fraud Office.

10. The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat. The Management Board shall invite the Chair of the Scientific Committee to attend its meetings without voting rights.

Article 26
第 26 條

Executive Director
執行長

1. The Executive Director shall be appointed by the Management Board, on the basis of a list of candidates proposed by the Commission after an open competition, following publication in the Official Journal of the European Communities and elsewhere of a call for expressions of interest, for a period of five years which shall be renewable. Before appointment the candidate nominated by the Management Board shall be invited without delay to make a statement before the European Parliament and answer questions put by members of this institution. The Executive Director may be removed from office by a majority of the Management Board.

2. The Executive Director shall be the legal representative of the Authority and shall be responsible for:

(a) the day-to-day administration of the Authority;

(b) drawing up a proposal for the Authority's work programmes in consultation with the Commission;

(c) implementing the work programmes and the decisions adopted by the Management Board;
(d) ensuring the provision of appropriate scientific, technical and administrative support for the Scientific Committee and the Scientific Panels;

(e) ensuring that the Authority carries out its tasks in accordance with the

requirements of its users, in particular with regard to the adequacy of the services provided and the time taken;

▼M1

(f) the preparation of the Authority's draft statement of estimates of revenue and expenditure, and the execution of its budget;

(f) the preparation of the statement of revenue and expenditure and the execution of the budget of the Authority;

(g) all staff matters;

(h) developing and maintaining contact with the European Parliament, and for ensuring a regular dialogue with its relevant committees.

▼M1

3. Each year, the Executive Director shall submit to the Management Board for approval:

(a) a draft general report covering all the activities of the Authority in the previous year;

(b) draft programmes of work.

The Executive Director shall, following adoption by the Management Board, forward the programmes of work to the European Parliament, the Council, the Commission and the Member States, and shall have them published.

The Executive Director shall, following adoption by the Management Board and by 15 June, forward the Authority's general report to the European Parliament, the Council, the Commission, the Court of Auditors, the European Economic and Social Committee and the Committee of the Regions, and shall have it published.

The Executive Director shall forward annually to the budgetary authority all information relevant to the outcome of the evaluation procedures.

▼M1 ——————

3. Each year, the Executive Director shall submit to the Management Board for approval:

(a) a draft general report covering all the activities of the Authority in the previous year;

(b) draft programmes of work;

(c) the draft annual accounts for the previous year;

(d) the draft budget for the coming year.
The Executive Director shall, following adoption by the Management Board, forward the general report and the programmes to the European Parliament, the Council, the Commission and the Member States, and shall have them published.

4. The Executive Director shall approve all financial expenditure of the Authority and report on the Authority's activities to the Management Board.

Article 27
第 27 條

Advisory Forum
諮詢論壇

1. The Advisory Forum shall be composed of representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority, on the basis of one representative designated by each Member State. Representatives may be replaced by alternates, appointed at the same time.

2. Members of the Advisory Forum may not be members of the Management Board.

3. The Advisory Forum shall advise the Executive Director in the performance of his duties under this Regulation, in particular in drawing up a proposal for the Authority's work programme. The Executive Director may also ask the Advisory Forum for advice on the prioritisation of requests for scientific opinions.

4. The Advisory Forum shall constitute a mechanism for an exchange of information on potential risks and the pooling of knowledge. It shall ensure close cooperation between the Authority and the competent bodies in the Member States in particular on the following items:

(a) avoidance of duplication of the Authority's scientific studies with Member States, in accordance with Article 32;

(b) in those circumstances identified in Article 30(4), where the Authority and a national body are obliged to cooperate;

(c) in the promoting of the European networking of organisations operating within the fields of the Authority's mission, in accordance with Article 36(1);

(d) where the Authority or a Member State identifies an emerging risk.

5. The Advisory Forum shall be chaired by the Executive Director. It shall meet regularly at the invitation of the Chair or at the request of at least a third of its members, and not less than four times per year. Its operational procedures shall be specified in the Authority's internal rules and shall be made public.

6. The Authority shall provide the technical and logistic support necessary for the Advisory Forum and provide the Secretariat for its meetings.

7. Representatives of the Commission's departments may participate in the work of the Advisory Forum. The Executive Director may invite representatives of the European Parliament and from other relevant bodies to take part.
Where the Advisory Forum discusses the matters referred to in Article 22(5)(b), representatives from competent bodies in the Member States which undertake tasks similar to those referred to in Article 22(5)(b) may participate in the work of the Advisory Forum, on the basis of one representative designated by each Member State.

Article 28
第 28 條

Scientific Committee and Scientific Panels
科學委員會和科學技術小組

1. The Scientific Committee and permanent Scientific Panels shall be responsible for providing the scientific opinions of the Authority, each within their own spheres of competence, and shall have the possibility, where necessary, of organising public hearings.

2. The Scientific Committee shall be responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure, in particular

with regard to the adoption of working procedures and harmonisation of working methods. It shall provide opinions on multisectoral issues falling within the competence of more than one Scientific Panel, and on issues which do not fall within the competence of any of the Scientific Panels.

Where necessary, and particularly in the case of subjects which do not fall within the competence of any of the Scientific Panels, the Scientific Committee shall set up working groups. In such cases, it shall draw on the expertise of those working groups when establishing scientific opinions.

3. The Scientific Committee shall be composed of the Chairs of the Scientific Panels and six independent scientific experts who do not belong to any of the Scientific Panels.

4. The Scientific Panels shall be composed of independent scientific experts. When the Authority is established, the following Scientific Panels shall be set up:

▼M3

(a) the Panel on food additives and nutrient sources added to food;

(a) the Panel on food additives, flavourings, processing aids and materials in contact with food;

(b) the Panel on additives and products or substances used in animal feed;

▼M2

(c) the Panel on plant protection products and their residues;

(c) the Panel on plant health, plant protection products and their residues;

(d) the Panel on genetically modified organisms;

(e) the Panel on dietetic products, nutrition and allergies;

(f) the Panel on biological hazards;

(g) the Panel on contaminants in the food chain;

(h) the Panel on animal health and welfare.

▼M2

(i) the Panel on plant health;

▼M3

(j) the Panel on food contact materials, enzymes, flavourings, and processing aids.

▼M4

The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).

The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request, in accordance with the procedure referred to in Article 58(2).

5. The members of the Scientific Committee who are not members of Scientific Panels and the members of the Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a three-year term of office, which shall be renewable, following publication in the *Official Journal of the European Communities*, in relevant leading scientific publications and on the Authority's website of a call for expressions of interest.

6. The Scientific Committee and the Scientific Panels shall each choose a Chair and two Vice-Chairs from among their members.

7. The Scientific Committee and the Scientific Panels shall act by a majority of their members. Minority opinions shall be recorded.

8. The representatives of the Commission's departments shall be entitled to be present in the meetings of the Scientific Committee, the Scientific Panels and their working groups. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.

9. The procedures for the operation and cooperation of the Scientific Committee and the Scientific Panels shall be laid down in the Authority's internal rules.

These procedures shall relate in particular to:

(a) the number of times that a member can serve consecutively on a Scientific Committee or Scientific Panel;

(b) the number of members in each Scientific Panel;

(c) the procedure for reimbursing the expenses of members of the Scientific Committee and the Scientific Panels;

(d) the manner in which tasks and requests for scientific opinions are assigned to the Scientific Committee and the Scientific Panels;

(e) the creation and organisation of the working groups of the Scientific Committee and the Scientific Panels, and the possibility of external experts being included in those working groups;

(f) the possibility of observers being invited to meetings of the Scientific Committee and the Scientific Panels;

(g) the possibility of organising public hearings.

SECTION 3
第三節

OPERATION
運作

Article 29
第 29 條

Scientific opinions
科學審查意見

1. The Authority shall issue a scientific opinion:
(a) at the request of the Commission, in respect of any matter within its mission, and in all cases where Community legislation makes provision for the Authority to be consulted;

(b) on its own initiative, on matters falling within its mission.

The European Parliament or a Member State may request the Authority to issue a scientific opinion on matters falling within its mission.

2. Requests referred to in paragraph 1 shall be accompanied by background information explaining the scientific issue to be addressed and the Community interest.

3. Where Community legislation does not already specify a time limit for the delivery of a scientific opinion, the Authority shall issue scientific opinions within the time limit specified in the requests for opinions, except in duly justified circumstances.

4. Where different requests are made on the same issues or where the request is not in accordance with paragraph 2, or is unclear, the Authority may either refuse, or propose amendments to a request for an opinion in consultation with the institution or Member State(s) that made the request. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

5. Where the Authority has already delivered a scientific opinion on the specific topic in a request, it may refuse the request if it concludes there are no new scientific elements justifying the re-examination. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

▼M4

6. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority. Those rules shall specify in particular:

(a) the procedure to be applied by the Authority to the requests referred to it;

(b) the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

The measure referred to in point (a), designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).

The guidelines referred to in point (b) shall be adopted in accordance with the regulatory procedure referred to in Article 58(2).

6. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority, in accordance with the procedure provided for in Article 58(2). These rules shall specify in particular:

(a) the procedure to be applied by the Authority to the requests referred to it;

(b) the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

7. The Authority's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.

Article 30
第 30 條

Diverging scientific opinions
分歧的科學審查意見

1. The Authority shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.

2. Where the Authority identifies a potential source of divergence, it shall contact the body in question to ensure that all relevant scientific information is shared and in order to identify potentially contentious scientific issues.

3. Where a substantive divergence over scientific issues has been identified and the body in question is a Community agency or one of the Commission's Scientific Committees, the Authority and the body concerned shall be obliged to cooperate with a view to either resolving the divergence or presenting a joint document to the Commission clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

4. Where a substantive divergence over scientific issues has been identified and the

body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

Article 31
第 31 條

Scientific and technical assistance
科學與技術性協助

1. The Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission. The tasks of providing scientific and technical assistance shall consist of scientific or technical work involving the application of well-established scientific or technical principles which does not require scientific evaluation by the Scientific Committee or a Scientific Panel. Such tasks may include in particular assistance to the Commission for the establishment or evaluation of technical criteria and also assistance to the Commission in the development of technical guidelines.

2. Where the Commission refers a request for scientific or technical assistance to the Authority, it shall specify, in agreement with the Authority, the time limit within which the task must be completed.

Article 32
第 32 條

Scientific studies
科學研究

1. Using the best independent scientific resources available, the Authority shall commission scientific studies necessary for the performance of its mission. Such studies shall be commissioned in an open and transparent fashion. The Authority shall seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination.

2. The Authority shall inform the European Parliament, the Commission and the Member States of the results of its scientific studies.

Article 33
第 33 條

Collection of data
資料彙集

1. The Authority shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields within its mission. This shall involve in particular the collection of data relating to:

(a) food consumption and the exposure of individuals to risks related to the consumption of food;

(b) incidence and prevalence of biological risk;

(c) contaminants in food and feed;

(d) residues.

2. For the purposes of paragraph 1, the Authority shall work in close cooperation with all organisations operating in the field of data collection, including those from applicant countries, third countries or international bodies.

3. The Member States shall take the necessary measures to enable the data they collect in the fields referred to in paragraphs 1 and 2 to be transmitted to the Authority.

4. The Authority shall forward to the Member States and the Commission appropriate recommendations which might improve the technical comparability of the data it receives and analyses, in order to facilitate consolidation at Community level.

5. Within one year following the date of entry into force of this Regulation, the Commission shall publish an inventory of data collection systems existing at Community level in the fields within the mission of the Authority.

The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular:

(a) for each system, the role which should be assigned to the Authority, and any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States;

(b) the shortcomings which should be remedied to enable the Authority to collect and summarise at Community level relevant scientific and technical data in the fields within its mission.

6. The Authority shall forward the results of its work in the field of data collection to the European Parliament, the Commission and the Member States.

Article 34
第 34 條

Identification of emerging risks
新生風險之鑑定

1. The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission.

2. Where the Authority has information leading it to suspect an emerging serious risk, it shall request additional information from the Member States, other Community agencies and the Commission. The Member States, the Community agencies concerned and the Commission shall reply as a matter of urgency and forward any relevant information in their possession.

3. The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.

4. The Authority shall forward the evaluation and information collected on emerging risks to the European Parliament, the Commission and the Member States.

Article 35
第 35 條

Rapid alert system
快速警報系統

To enable it to perform its task of monitoring the health and nutritional risks of foods as effectively as possible, the Authority shall be the recipient of any messages forwarded via the rapid alert system. It shall analyse the content of such messages with a view to providing the Commission and the Member States with any information required for the purposes of risk analysis.
為盡可能有效監控健康和食品的營養風險的任務，本局透過迅速的警示系統傳遞所有接收之訊息，並分析消息的內容，提供執委會和會員國所需風險分析要求的訊息。

Article 36
第 36 條

Networking of organisations operating in the fields within the Authority's mission
在該局使命涵蓋範圍內行動之組織網路

1. The Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission.

2. The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public of competent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.

▼M4

3. The Commission, after consulting the Authority, shall lay down rules establishing the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support. Those measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 58(3).

Other implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the regulatory procedure referred to in Article 58(2).

3. The implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 58(2). Those rules shall specify, in particular, the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support.

4. Within one year following the entry into force of this Regulation, the Commission shall publish an inventory of Community systems existing in the fields within the mission of the Authority which make provision for Member States to carry out certain tasks in the field of scientific evaluation, in particular the examination of authorisation dossiers. The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular, for each system, any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States.

SECTION 4
第四節

INDEPENDENCE, TRANSPARENCY, CONFIDENTIALITY AND COMMUNICATION
獨立、透明化、機密與通知

Article 37
第 37 條

Independence
獨立

1. The members of the Management Board, the members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered

prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

2. The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

3. The members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their working groups shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda.

Article 38
第 38 條

Transparency
透明化

1. The Authority shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay:
(a) agendas and minutes of the Scientific Committee and the Scientific Panels;

(b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included;

(c) without prejudice to Articles 39 and 41, the information on which its opinions are based;

(d) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest

made in relation to items on the agendas of meetings;

(e) the results of its scientific studies;

(f) the annual report of its activities;

(g) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

2. The Management Board shall hold its meetings in public unless, acting on a proposal from the Executive Director, it decides otherwise for specific administrative points of its agenda, and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.

3. The Authority shall lay down in its internal rules the practical arrangements for implementing the transparency rules referred to in paragraphs 1 and 2.

Article 39
第 39 條

Confidentiality
機密性

1. By way of derogation from Article 38, the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health.

2. Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall be subject to the requirements of confidentiality pursuant to Article 287 of the Treaty.

3. The conclusions of the scientific opinions delivered by the Authority relating to foreseeable health effects shall on no account be kept confidential.

4. The Authority shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.

Article 40
第 40 條

Communications from the Authority
傳達訊息

1. The Authority shall communicate on its own initiative in the fields within its mission without prejudice to the Commission's competence to communicate its risk management decisions.

2. The Authority shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Authority shall develop and disseminate information material for the general public.

3. The Authority shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process.

The Authority shall publish all opinions issued by it in accordance with Article 38.

4. The Authority shall ensure appropriate cooperation with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

▼M1

Article 41

Access to documents

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding access to European Parliament, Council and Commission documents (27) shall apply to documents held by the Authority.

2. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 within six months after the entry into force of Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22

July 2003 amending Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (28).

3. Decisions taken by the Authority pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the EC Treaty respectively.

Article 41
第 41 條

Access to documents
文件的取用

1. The Authority shall ensure wide access to the documents which it possesses.

2. The Management Board, acting on a proposal from the Executive Director, shall adopt the provisions applicable to access to the documents referred to in paragraph 1, taking full account of the general principles and conditions governing the right of access to the Community institutions' documents.

Article 42
第 42 條

Consumers, producers and other interested parties
消費者、製造商及其他利害關係人

The Authority shall develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties.

SECTION 5
第五節

FINANCIAL PROVISIONS
財政規定

Article 43
第 43 條

Adoption of the Authority's budget

該局預算之通過

1. The revenues of the Authority shall consist of a contribution from the Community and, from any State with which the Community has concluded the agreements referred to in Article 49, and charges for publications, conferences, training and any other similar activities provided by the Authority.

2. The expenditure of the Authority shall include the staff, administrative, infrastructure and operational expenses, and expenses resulting from contracts entered into with third parties or resulting from the financial support referred to in Article 36.

▼M1

3. The Executive Director shall draw up, in good time before the date referred to in paragraph 5, a draft statement of estimates of the Authority's revenue and expenditure for the following financial year and shall forward it to the Management Board, together with the establishment plan.

4. Revenue and expenditure shall be in balance.

5. Each year the Management Board, on the basis of a draft statement of estimates of revenue and expenditure, shall produce a statement of estimates of revenue and expenditure of the Authority for the following financial year. This statement of estimates, which shall include a draft establishment plan together with the provisional work programmes, shall be forwarded by 31 March at the latest by the Management Board to the Commission and to the countries with which the Community has concluded agreements in accordance with Article 49.

6. The statement of estimates shall be forwarded by the Commission to the European Parliament and the Council (hereinafter referred to as the budgetary authority) together with the preliminary draft general budget of the European Union.

▼M1

7. On the basis of the statement of estimates, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.

8. The budgetary authority shall authorise the appropriations for the subsidy to the Authority.

The budgetary authority shall adopt the establishment plan for the Authority.

9. The budget shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.

10. The Management Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of the budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of six weeks from the date of notification of the project.

3. In good time, before the date referred to in paragraph 5, the Executive Director shall draw up an estimate of the Authority's revenue and expenditure for the coming financial year, and shall forward it to the Management Board, accompanied by a provisional list of posts.

4. Revenue and expenditure shall be in balance.

5. By 31 March each year at the latest, the Management Board shall adopt the draft estimates including the provisional list of posts accompanied by the preliminary work programme and forward them to the Commission, and the States with which the Community has concluded the agreements referred to in Article 49. On the basis of that draft, the Commission shall enter the relevant estimates in the preliminary draft general budget of the European Union to be put before the Council pursuant to Article 272 of the Treaty.

6. After the adoption of the general budget of the European Union by the budgetary authority, the Management Board shall adopt the Authority's final budget and work programme, adjusting them where necessary to the Community's contribution. It shall forward them without delay to the Commission and the budgetary authority.

▼M1

Article 44

Implementation of the Authority's budget

1. The Executive Director shall implement the Authority's budget.

2. By 1 March at the latest following each financial year, the Authority's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of the general Financial Regulation.

3. By 31 March at the latest following each financial year, the Commission's accounting officer shall forward the Authority's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for the financial year shall also be forwarded to the European Parliament and the Council.

4. On receipt of the Court of Auditors' observations on the Authority's provisional accounts under Article 129 of the general Financial Regulation, the Executive Director shall draw up the Authority's final accounts under his own responsibility and submit them to the Management Board for an opinion.

5. The Management Board shall deliver an opinion on the Authority's final accounts.

6. The Executive Director shall, by 1 July at the latest following each financial year, forward the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.

7. The final accounts shall be published.

8. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September at the latest. He shall also send this reply to the Management Board.

9. The Executive Director shall submit to the European Parliament, at the latter's request, all information necessary for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 146(3) of the general Financial Regulation.

10. The European Parliament, on a recommendation from the Council acting by a qualified majority, shall, before 30 April of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.

Article 44
第 44 條

Implementation of the Authority's budget

該局預算之執行

1. The Executive Director shall implement the Authority's budget.

2. Control of commitment and payment of all expenditure and control of the existence and recovery of all the Authority's revenue shall be carried out by the Commission's financial controller.

3. By 31 March each year at the latest, the Executive Director shall forward to the Commission, the Management Board and the Court of Auditors the detailed accounts for all the revenue and expenditure in respect of the previous financial year.

The Court of Auditors shall examine the accounts in accordance with Article 248 of the Treaty. It shall publish each year a report on the Authority's activities.

4. The European Parliament, acting on a recommendation from the Council, shall give a discharge to the Authority's Executive Director in respect of the implementation of the budget.

Article 45
第 45 條

Fees received by the Authority
該局之收費

Within three years following the date of entry into force of this Regulation and after consulting the Authority, the Member States and the interested parties, the Commission shall publish a report on the feasibility and advisability of presenting a legislative proposal under the co-decision procedure and in accordance with the Treaty and for other services provided by the Authority.

SECTION 6
第六節

GENERAL PROVISIONS
一般規定

Article 46
第 46 條

Legal personalityand privileges
法人格及特權

1. The Authority shall have legal personality. In all Member States it shall enjoy the widest powers granted by law to legal persons. In particular, it may acquire and dispose of movable and immovable property and institute legal proceedings.

2. The Protocol on the privileges and immunities of the European Communities shall apply to the Authority. Article 47

Article 47
第 47 條
Liability
法定責任

1. The contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority.

2. In the case of non-contractual liability, the Authority shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage.

3. The personal liability of its servants towards the Authority shall be governed by the relevant provisions applying to the staff of the Authority.

Article 48
第 48 條

Staff
工作人員

1. The staff of the Authority shall be subject to the rules and regulations applicable to

officials and other staff of the European Communities.

2. In respect of its staff, the Authority shall exercise the powers which have been devolved to the appointing authority.

Article 49
第 49 條

Participation of third countries
第三國之參與

The Authority shall be open to the participation of countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by this Regulation.

Arrangements shall be made under the relevant provisions of those agreements, specifying in particular the nature, extent and manner in which these countries will participate in the Authority's work, including provisions relating to participation in the networks operated by the Authority, inclusion in the list of competent organisations to which certain tasks may be entrusted by the Authority, financial contributions and staff.

CHAPTERIV
第 IV 章

RAPID ALERT SYSTEM, CRISIS MANAGEMENT AND EMERGENCIES
快速警報系統、危機管理與緊急措施

SECTION 1
第一節

RAPID ALERT SYSTEM
快速警報系統

Article 50
第 50 條

Rapid alert system
快速警報系統

1. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the Authority. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network. The Commission shall be responsible for managing the network.
1. 快速警示通報系統為當某食品或飼料如可能直接或間接對人類健康產生風險時，能快速將產品通報的網絡組織。它應與會員國、執委會以及本局有關。會員國、執委會與本局應各自指定聯絡處，該處應為網狀組織的會員。執委會應負責網絡組織管理。

2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network.
當會員擁有任何與人類經由食物的攝取對健康產生直接或間接危害之資訊時，這個資訊將會在快速警示通報系統之下直接的告知執委會。執委會應直接的傳送資訊給各網絡組織會員。

The Authority may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate risk management action by the Member States.
本局可能會補充一些科學或技術上之資訊，使會員國能更快速適當的執行風險管理功能。

3. Without prejudice to other Community legislation, the Member States shall immediately notify the Commission under the rapid alert system of:
在不違反其他歐盟所制定之法令的情形下，會員國應將在下列情況下，透過快速警示通報系統，立即的通報執委會：

(a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;
(a)採取任何措施以限制產品上市銷售，或是強制使產品下架與食品回收等，達成其為保護人類健康而需採取快速行動；

(b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;
(b)任何專業人員之建議或協議以自願之方式達成預防、限制或促使市面產品或食品或飼料之最終使用所造成之人類健康嚴重風險而需採取快速行動；

(c) any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.
(c)在歐盟的邊境，其權責機關對於任何一批與人類健康有直接或間接危害相關之產品無法通關並退運。

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn.
當通知發佈時，將會伴隨著會員國主管當局對於行動訊息內容詳細的原因說明。這個說明將會被密切注意，且適時地被補充其相關資訊，尤其當通知訊息內容已被修改或撤銷。

The Commission shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs.
執委會將立即地傳送通知至網絡會員，並在第 1 與第 2 小段下方補充一些已被認定之相關資訊標準。

Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Commission shall immediately notify all the border posts within the European Union, as well as the third country of origin.
當歐盟邊境範圍內有任何一批貨品遭到權責機關退回時，執委會將會馬上通報境內所有的歐盟國及第三原產國。

4. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Commission shall provide the latter with the appropriate information.
當被通知的食品或飼料隸屬於此快速警示通訊系統下時，通知訊息會被發送至第

三國，而執委會將會提供適當的資訊告知第三國。

5. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network.
5.會員國將立即通報執委會，在快速警示通報系統下，執行或實施通報與補充資訊皆遵循快速通報系統。執委會亦將立即傳送此資訊至網絡會員。

6. Participation in the rapid alert system may be opened up to applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.
6.快速警示通報系統的參與可開放至申請人的國家、第三國或國際組織。在一致同意的基礎下，歐盟與他們的國家或是國際組織之間，將准許這些一致認定的程序。

Article 51
第 51 條

Implementing measures
施行措施

The measures for implementing Article 50 shall be adopted by the Commission, after discussion with the Authority, in accordance with the procedure referred to in Article 58(2). These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information.
依第58條(2)程序的第50條法規的執行措施,在與本局商討之後將被執委會採用。這些措施將有明確說明，尤其是特定的條件與程序，並可適用於傳達通知與補充資訊。

Article 52
第 52 條

Confidentiality rules for the rapid alert system
快速警報系統適用之機密準則

1. Information, available to the members of the network, relating to a risk to human health posed by food and feed shall in general be available to the public in accordance with the information principle provided for in Article 10. In general, the public shall have access to information on product identification, the nature of the risk and the measure taken.
1. 引起人類健康危害的食品相關資訊可被網絡組織會員所利用，此類資訊提供給歐盟的原則在第 10 條法規中有提及。一般而言，歐盟將能接觸到產品辨別、危險性質與採取措施相關之訊息。

However, the members of the network shall take steps to ensure that members of their staff are required not to disclose information obtained for the purposes of this Section which by its nature is covered by professional secrecy in duly justified cases, except for information which must be made public, if circumstances so require, in order to protect human health.
總之，網絡組織會員將可採取措施去確保會員國當中的工作人員不得透露所獲得之正式的專業機密案件所涵蘊之資訊。除了當環境需要，且為了保護人類健康而被大眾使用之資訊以外。

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant to the effectiveness of market surveillance and enforcement activities in the field of food and feed. The authorities receiving information covered by professional secrecy shall ensure its protection in conformity with paragraph 1.
2. 專業機密的保護將不會阻礙權責機關對於市場監督相關資訊之有效性宣導以及實際上對於食品之執行力。當權責機關接收到專業機密所涵蓋之資訊時，必須確保它的防護與第一段相符合。

SECTION 2
第二節

EMERGENCIES
緊急措施

Article 53
第 53 條

Emergency measures for food and feed of Community origin or imported from a third country

源於歐盟或自第三國進口之食品與飼料之緊急措施

1. Where it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, acting in accordance with the procedure provided for in Article 58(2) on its own initiative or at the request of a Member State, shall immediately adopt one or more of the following measures, depending on the gravity of the situation:

很明顯的，起因為歐盟或是第三國進口之食品有可能構成人類健康、動物健康或環境的嚴重危害。會員國擔心無法有效的以某些措施來控制此種危害，因此執委會主動的或是會員國要求依照第58條(2)之程序，依情勢之重要性將立即採取一種或多種的措施。

(a) in the case of food or feed of Community origin:

（a）起因於歐盟之食品或飼料的案件

(i) suspension of the placing on the market or use of the food in question;

（i）中止市場出售或是問題食品的利用

(ii) suspension of the placing on the market or use of the feed in question;

（ii）中止市場出售或是問題飼料的利用

(iii) laying down special conditions for the food or feed in question;

（iii）問題食品或飼料擬訂特定條件下

(iv) any other appropriate interim measure;

（iv）任何其他適當的暫訂措施

(b) in the case of food or feed imported from a third country:

（b）從第三國進口食品或飼料的案件

(i) suspension of imports of the food or feed in question from all or part of the third country concerned and, where applicable, from the third country of transit;

（i）中止全部或部分第三國問題食品或飼料進口，若為適用之食品，則由第三

國運輸。

(ii) laying down special conditions for the food or feed in question from all or part of the third country concerned;
（ii）擬訂第三國進口之全部或部分特殊狀態之問題食品或飼料

(iii) any other appropriate interim measure.
（iii）任何其他適當的暫定措施

2. However, in EMERGENCIES, the Commission may provisionally adopt the measures referred to in paragraph 1 after consulting the Member State(s) concerned and informing the other Member States.
2. 總之，在緊急事件當中，執委會可諮詢過會員國之意見後，臨時採取參照第一段之措施，並告知其他的會員國。

As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 58(2), and the reasons for the Commission's decision shall be made public without delay.
所採取之措施將盡快且不超過 10 個工作天被確認、改正、撤銷或者根據第 58 條（2）程序加以延伸，而執委會將會把所決策之原因立即公開。

Article 54
第 54 條

Other emergency measures
其他緊急措施

1. Where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.
1. 當會員國正式告知執委會需要採取緊急措施，而執委會並沒有依照第 53 條行動時，會員國可以採取臨時保護措施。在這個事件裡，將直接告知其他的會員國與執委會。

2. Within 10 working days, the Commission shall put the matter before the Committee set up in Article 58(1) in accordance with the procedure provided for in Article 58(2)

with a view to the extension, amendment or abrogation of the national interim protective measures.
2. 在 10 個工作天內，執委會必須在第 58 條（1）建立之前，先依據第 58（2）程序為條件作為延伸的目的，改正或廢除該國臨時保護措施。

3. The Member State may maintain its national interim protective measures until the Community measures have been adopted.
3. 會員國可維持該國國內之臨時保護措施，直到歐盟措施已經被採取為止。

SECTION 3
第三節

CRISIS MANAGEMENT
危機管理

Article 55
第 55 條

General plan for crisis management
危機管理之整體計畫

1. The Commission shall draw up, in close cooperation with the Authority and the Member States, a general plan for crisis management in the field of the safety of food and feed (hereinafter referred to as 'the general plan').
執委會將終止和官方當局與會員國的密切計畫，在食品及飼料安全相關領域中之整體危機管理計劃（以下稱為整體計畫）。

2. The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54.
2. 整體計畫將明確說明工作性質，包括不可能被防止、消滅或減少至可接受程度之對人類產生直接或間接危害食品和飼料。或無法適當的的被經由第53與54條法規單獨的管理。

The general plan shall also specify the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.

整體計畫亦將明確說明危機管理必需之實際程序，包括明確被應用的原則以及通訊策略。

Article 56
第 56 條

Crisis unit
危機小組

1. Without prejudice to its role of ensuring the application of Community law, where the Commission identifies a situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot adequately be managed solely by way of the application of Articles 53 and 54, it shall immediately notify the Member States and the Authority.
1. 以不違反歐盟法規的應用下，執委會定義了食品或飼料對人類健康有直接或間接危害，由現有條款風險不能被預防、消除或減少，或適當的被經由第 53 與 54 條法規單獨的管理，將立即通報會員國與政府當局。

2. The Commission shall set up a crisis unit immediately, in which the Authority shall participate, and provide scientific and technical assistance if necessary.
2. 執委會將立即建立一個危機小組，權責單位將參與其中，若有必要的話，將提供科學與技術上的支援。

Article 57
第 57 條

Tasks of the crisis unit
危機小組的任務

1. The crisis unit shall be responsible for collecting and evaluating all relevant information and identifying the options available to prevent, eliminate or reduce to an acceptable level the risk to human health as effectively and rapidly as possible.
1.危機小組將負責收集和評估全部相關訊息，並判定風險可得到預防、排除或減少，且盡可能有效並迅速消滅或降低可接受的範圍至人類健康所產生的危害。

2. The crisis unit may request the assistance of any public or private person whose expertise it deems necessary to manage the crisis effectively.
2. 危機小組可要求大眾或私人的支援，此專業技術被認為必須能夠有效管理危

機。

3. The crisis unit shall keep the public informed of the risks involved and the measures taken.
3. 危機小組將告知大眾有關危害以及所採取的措施。

CHAPTERV
第 V 章

PROCEDURES AND FINAL PROVISIONS
程序與最終條款

SECTION 1
第一節

COMMITTEE AND MEDIATION PROCEDURES
委員會與調解程序

Article 58
第 58 條

Committee
委員會

1. The Commission shall be assisted by a Standing Committee on the Food Chain and Animal Health, hereinafter referred to as the 'Committee', composed of representatives of the Member States and chaired by the representative of the Commission. The Committee shall be organised in sections to deal with all relevant matters.
1. 在食物鏈與動物健康方面，執委會將由常務委員會幫助，在下文被稱為「委員會」，是由會員國的代表組成且由執委會中之代表主持。委員會將組織處理全部相關事宜。

▼M4

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

2.此段落之參考文獻，依據第8條之條文下，在決議1999/468/EC第5條及第7條下應該被採用，依據其中的第7、8條。1999/468/EC第5條（6）將有3個月期間做準備。

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
3. 此段落之參考文獻，依據第 8 條之條文下，在決議 1999/468/EC 第 5a(1)條至及(4)下應該被採用。

2. Where reference is made to this paragraph, the procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Articles 7 and 8 thereof.
2.此段落之參考文獻，在決議1999/468/EC第5條下應該被採用，依據其中的第7、8條。

3. The period provided for in Article 5(6) of Decision 1999/ 468/EC shall be three months.
3. 1999/468/EC 第 5 條（6）將有 3 個月期間做準備。

Article 59
第 59 條

Functions assigned to the Committee
委員會受命之任務

The Committee shall carry out the functions assigned to it by this Regulation and by other relevant Community provisions, in the cases and conditions provided for in those provisions. It may also examine any issue falling under those provisions, either at the initiative of the Chairman or at the written request of one of its members.
在這些條款的情況與狀況下，委員會將透過法規與其他相關的歐盟條款進行工作的分配。其也可檢視在此法規中任何會產生的爭議，當然也包括主席之創制權或是會員的書面申請。

Article 60
第 60 條

Mediation procedure
調解程序

1. Without prejudice to the application of other Community provisions, where a Member State is of the opinion that a measure taken by another Member State in the field of food safety is either incompatible with this Regulation or is likely to affect the functioning of the internal market, it shall refer the matter to the Commission, which will immediately inform the other Member State concerned.

1. 為了不使其他歐盟條款的運用受到損害，當會員國認為其他會員國在食品安全領域之採用標準與法規無法同時成立，或是有可能影響國內市場之功能，它將引導執委會立即通知其他相關的會員國。

2. The two Member States concerned and the Commission shall make every effort to solve the problem. If agreement cannot be reached, the Commission may request an opinion on any relevant contentious scientific issue from the Authority. The terms of that request and the time limit within which the Authority is requested to give its opinion shall be established by mutual agreement between the Commission and the Authority, after consulting the two Member States concerned.

2. 二個相關的會員國與執委會間將盡力解決問題。若無法達成共識，執委會可以請求權責機關提供每一個與科學相關爭議的意見。在請求與期限的條件內，權責機關在諮詢相關二個會員國後，會將執委會與權責機關之意見經由雙方同意建立。

SECTION 2
第二節

FINAL PROVISIONS
最終的條款

Article 61
第 61 條

Review clause
條款複審

1. Before 1 January 2005 and every six years thereafter, the Authority, in collaboration with the Commission, shall commission an independent external evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the working practices and the impact of the Authority. The evaluation will take into account the views of the stakeholders, at both Community and national level.

The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority and its working practices. The evaluation and the recommendations shall be made public.

2. Before 1 January 2005, the Commission shall publish a report on the experience acquired from implementing Sections 1 and 2 of Chapter IV.

3. The reports and recommendations referred to in paragraphs 1 and 2 shall be forwarded to the Council and the European Parliament.

Article 62
第 62 條

References to the European Food Safety Authority and to the Standing Committee on the Food Chain and Animal Health
歐盟食品安全局和食品鏈與動物健康常務委員會之參考

1. Every reference in Community legislation to the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Veterinary Committee, the Scientific Committee on Pesticides, the Scientific Committee on Plants and the Scientific Steering Committee shall be replaced by a reference to the European Food Safety Authority.

2. Every reference in Community legislation to the Standing Committee on Foodstuffs, the Standing Committee for Feeding-stuffs and the Standing Veterinary Committee shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.

Every reference to the Standing Committee on Plant Health in Community legislation based upon and including Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, 90/642/EEC and 91/ 414/EEC relating to plant protection products and the setting of maximum residue levels shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.

3. For the purpose of paragraphs 1 and 2, ‘Community legislation’ shall mean all Community Regulations, Directives and Decisions.

4. Decisions 68/361/EEC, 69/414/EEC and 70/372/EEC are hereby repealed.

Article 63
第 63 條

Competence of the European Agency for the Evaluation of Medicinal Products
歐盟藥品評估局的權限

This Regulation shall be without prejudice to the competence conferred on the European Agency for the Evaluation of Medicinal Products by Regulation (EEC) No 2309/93, Regulation (EEC) No 2377/90, Council Directive 75/319/EEC (1) and Council Directive 81/851/EEC (2).

Article 64
第 64 條

Commencement of the Authority's operation
歐盟當局運作的開始

The Authority shall commence its operations on 1 January 2002.

Article 65
第 65 條

Entry into force
生效日

This Regulation shall enter into force on the 20th day following that of its publication in the Official Journal of the European Communities.

Articles 11 and 12 and Articles 14 to 20 shall apply from 1 January 2005.

Articles 29, 56, 57 and 60 and Article 62(1) shall apply as from the date of appointment of the members of the Scientific Committee and of the Scientific Panels which shall be announced by means of a notice in the ‘C’ series of the Official Journal.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 January 2002.
For the European Parliament
The President
P. COX
For the Council
The President
J. PIQUE I CAMPS